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Filed : December 14, 2000

REMARKS

By way of summary, Claims 1–10, 21, 29–33, 60–71, and 74 are pending in this application. The Office Action dated January 18, 2007 rejected Claims 1–10, 21, 29–33, 60–71, and 74 as being anticipated under 35 U.S.C. § 102(e). By this Amendment, Claim 29 has been amended and Claim 75 has been added. By way of the foregoing amendments and following remarks, it is believed that Claims 1–10, 21, 29–33, 65–71, and 74–75 are patentably distinguished over the cited reference, and Applicant respectfully requests allowance of the pending claims.

A. Claim Amendments

In this Amendment, Claim 29 has been amended to further define the subject matter for which protection is sought and to expedite issuance of a patent. The Applicant respectfully submits that the claims as previously pending are patentably distinguished over the cited references or any combination thereof. However, to expedite prosecution, Applicant has amended the claims in order to clarify the features of Applicant's claimed invention. Applicant reserves the right to pursue the previously unamended claims or claims of broader scope at a later date.

Claim 75 has been added by this Amendment. Applicant respectfully submits that the added claim reads upon the previously prosecuted rotational medical device without introducing any new matter.

B. §102(e) Rejection of Claims under Nash (U.S. Patent No. 5,779,721)

The outstanding Office Action rejected Claims 1–10, 21, 29–33, 65–71, and 74 under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 5,779,721 to Nash. Nash discloses a system including an instrument within a guide catheter having a working head (“e.g., a rotary impacting impeller located within an apertured shroud”) and a debris extraction sub-system with a differential flow of infusate liquid to establish an unbalanced flow adjacent the working head to enable the catheter to be steered hydrodynamically and to aspirate debris from the working field of the instrument. Nash Abstract.

The Examiner cites an embodiment in Nash Figs. 1-3, which is provided for the Examiner's convenience below.



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Applicant respectfully traverses this rejection because Nash fails to identically teach every element of the rejected claims. A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631; see M.P.E.P. § 2131. Applicant also submits that Nash fails to render obvious the rejected claims for the reasons discussed below.

1. **Independent Claim 1 is not anticipated nor rendered obvious by Nash**

Claim 1 recites, among other things, “a sensor on the device in electrical communication with an indicator, for indicating resistance to rotation of either the rotatable element or rotatable cutter.” For example, in one embodiment, Applicant’s specification describes an LED that illuminates in response to an overload condition i.e., under a high resistance to rotation (page 37 lines 1 to page 38 line 18 and Fig. 1 of the application as filed).

The Office Action states that “Nash discloses in figures 1-3, ... a sensor (located at 28, 74, 76) in electrical communication with a [sic] an indicator for indicating resistance to rotation of either to [sic] rotatable element (42) or rotatable cutter (32).” Office Action p. 2. However, in the rejection the Examiner has provided no specific example in Nash of an indicator for indicating resistance to rotation which is in electrical communication with a sensor. The rejection relies on no specific teaching or suggestion in Nash, fails to explain how such indicator would be implemented into the Nash device, and fails to consider the significant and innovative reconstruction that would be required to modify the Nash device in order to meet the limitations of Claim 1.

The Nash device has no structural equivalent to the claimed indicator. In the rejection the Examiner has provided no specific example of where in Nash the device indicates resistance to rotation. Rather, as evidence of disclosure of this claim limitation, the Examiner has provided a reference to about two columns of the Nash specification (col. 8 line 20 to col. 9 line 37). In the Examiner’s cited passage of Nash, the atherectomy device is powered by an air turbine motor (70) that drives the drive sub-system (28). Air is provided from a source (not shown) via an associated regulator (74) and a conventional control valve (76). A pressure gauge (78) is provided in the air supply circuit upstream of the valve (76). There is no description in Nash of structure that indicates any resistance to rotation. The only measuring structure in this circuit, the

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pressure gauge (78), is not necessarily balanced with valve flow, turbine, and connecting conduit resistance such that the combination might potentially indicate resistance to rotation, if indeed it were even possible to do so.

For the foregoing reasons, Applicant respectfully submits that the Nash reference does not disclose, teach, or suggest any "sensor on the device in electrical communication with an indicator, for indicating resistance to rotation of either the rotatable element or rotatable cutter," as recited in Claim 1. Therefore, it is respectfully submitted that Nash does not teach or suggest all the limitations of Claim 1, and withdrawal of the rejection under 35 U.S.C. § 102(e) is respectfully requested.

2. Independent Claim 21 is not anticipated nor rendered obvious by Nash

The Office Action states, regarding a limitation of Claim 21, "Nash discloses in figures 1-3, . . . an aspiration lumen (at Q2 of fig. 3) . . . wherein the cross-sectional area of the aspiration lumen (Q2) is being at least about 35% of the cross-sectional area of the tubular body (24)." Office Action, page 2. However, there is no teaching in Nash for an aspiration lumen that is sized to be "at least 35% of the cross-sectional area of the tubular body." The Office Action fails to identify the disclosure, specific teaching or suggestion in Nash in support of this rejection, and Applicant was unable to identify any such support.

The Examiner asserts that the space between the outer surface of the catheter (22) and the inner surface of the guide catheter (24) defines an aspiration lumen (Q2). In order to determine the cross-sectional area of the space labeled Q2 it is necessary to have both dimensions. The Nash disclosure includes an outer dimension for the aspiration lumen: "As best seen in FIG. 4 the atherectomy catheter includes a jacket 34 which is formed of any suitable material, e.g., plastic, and has a small outside diameter. In the preferred embodiment shown herein, the outside diameter of the jacket 34 is approximately 1.5 mm (5 French)." Nash col. 6, ll. 42-46. Although Nash discloses a range for outer diameters for the guide catheter (24), it does not disclose any inside diameter for the lumen inside the guide catheter (24): "the guide catheter 24 is of any conventional construction. In the preferred embodiment shown in FIG. 1 it is a 10F to 12F catheter." Nash col. 8, ll. 10-12. As is recognized in the art, "French size" is a scale used to identify the outer diameter of a catheter. French scale units are obtained by multiplying the outer diameter of the catheter in mm by 3. Likewise, multiplying the French size by .33 will give the

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outer diameter of the catheter in mm. Nash discloses no inside dimension for the guide catheter (24), therefore it is impossible to determine the cross-sectional area of the aspiration lumen (Q2).

Furthermore, while some figures illustrate a space ("Q2") between the atherectomy catheter (22) and the guide catheter (24), there is no disclosure, teaching, or suggestion that it comprises at least 35% of the cross-sectional area of the tubular body. Nash does not state that the drawings are to scale, and "when the reference does not disclose that the drawings are to scale and is silent as to dimensions, arguments based on measurement of the drawing features are of little value." See M.P.E.P. § 2125 (citing *Hockerson-Halberstadt, Inc. v. Avia Group Int'l*, 222 F.3d 951, 956, 55 USPQ2d 1487, 1491 (Fed. Cir. 2000)). Thus, support for the rejection cannot be based solely on the drawings, and Applicant respectfully submits that there is no written support for the rejection.

Therefore, it is respectfully submitted that Nash does not teach or suggest all the limitations of Claim 21, and withdrawal of the rejection under 35 U.S.C. § 102(e) is respectfully requested.

3. Independent Claim 29 is not anticipated nor rendered obvious by Nash

The Office Action states, regarding a limitation of Claim 29, "Nash discloses in figures 1-3, ... a rotatable cutter (32) disposed at the distal end of said tubular body (22, 24)." Office Action, page 2. However, Claim 29 recites, among other things, "a rotatable cutter disposed within the tubular body at the distal end of the body." The Nash working head (32) ("e.g., a rotary impacting impeller located within an apertured shroud") is shown in all Nash figures as being housed in and extending distally beyond a cylindrical shroud (56), not the tubular body (22). Nash Abstract and Figures 1-5. Nash states, "The working head is located within a cylindrical shroud 56 (FIGS. 3 and 4) fixedly mounted on the front of the bushing 38. The shroud 56 includes a cylindrical sidewall portion 58 and a generally conical distal wall portion 60 terminating in a circular opening 62 in the distal end thereof. ... The distal arcuate portion of the impeller tip 54 projects out of the central or front opening 62." Nash col. 7, ll. 14-21. Thus, the Nash working head (32) is not "disposed within the tubular body." Applicant respectfully submits that the Nash reference does not disclose, teach, or suggest any "rotatable cutter disposed within the tubular body" as recited in Claim 29.

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Furthermore, the Office Action states, regarding a limitation of Claim 29, "Nash discloses in figures 1-3, . . . an aspiration lumen (at Q2 of fig. 3)." Office Action, page 2. The Examiner asserts that the space between the outer surface of the catheter (22) and the inner surface of the guide catheter (24) defines an aspiration lumen (Q2). However, Claim 29 as amended recites, among other things, "an axially extending annular aspiration channel defined by and located between the rotatable element and the tubular body." As defined by the Examiner, Nash has axially extending annular aspiration channel (Q2) extending between the atherectomy catheter 22 and the guide catheter 24. This channel does not extend between the Nash rotatable element (42) and the tubular body (22 or 24). Thus, Applicant respectfully submits that the Nash reference does not disclose, teach, or suggest any "rotatable cutter disposed within the tubular body" as recited in Claim 29.

Therefore, it is respectfully submitted that Nash does not teach or suggest all the limitations of Claim 29, and withdrawal of the rejection under 35 U.S.C. § 102(e) is respectfully requested.

4. Independent Claim 60 is not anticipated nor rendered obvious by Nash

The Office Action states that "Nash discloses in figures 1-3, . . . a sensor (located at 28, 74, 76) in electrical communication with a [sic] an indicator for indicating resistance to rotation of either to [sic] rotatable element (42) or rotatable cutter (32) and wherein the motor control circuit (70) is capable of disengaging the motor rotation from the cutter (32) where [sic] indicates an overload condition." Office Action p. 2. Claim 60 recites, among other things, "a sensor on the device in electrical communication with a motor control circuit, wherein the motor control circuit is capable of receiving a signal from the sensor for indicating an operating condition based upon resistance to rotation of either the rotatable element or rotatable cutter and wherein the motor control circuit is capable of disengaging the motor rotation from the cutter in the event the operating condition indicates an overload condition." However, as previously discussed above in relation to Claim 1, in the rejection the Examiner has provided no specific example in Nash of an indicator in electrical communication with a sensor for indicating resistance to rotation. As discussed above in relation to Claim 1, the rejection relies on no specific teaching or suggestion in Nash, fails to explain how such an indicator would be implemented into the Nash device, and fails to consider the significant and innovative reconstruction that would be required to modify

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the Nash device in order to meet the limitations of Claim 60. Furthermore, Nash does not disclose disengaging the motor rotation from the cutter in any situation.

Applicant respectfully submits that the Nash reference does not disclose, teach, or suggest any "sensor on the device in electrical communication with a motor control circuit, wherein the motor control circuit is capable of receiving a signal from the sensor for indicating an operating condition based upon resistance to rotation of either the rotatable element or rotatable cutter and wherein the motor control circuit is capable of disengaging the motor rotation from the cutter in the event the operating condition indicates an overload condition," as recited in Claim 60. Therefore, it is respectfully submitted that Nash does not teach or suggest all the limitations of Claim 60, and withdrawal of the rejection under 35 U.S.C. § 102(e) is respectfully requested.

5. Independent Claim 65 is not anticipated nor rendered obvious by Nash

Claim 65 recites, in part, an elongated tubular body, "the elongated tubular body defining an aspiration channel . . . a control disposed at the proximal end of the tubular body, the control including a connecting hub, the connecting hub coupling the tubular body to the control such that the tubular body may rotate relative to the control during operation." Nash, however, fails to teach a hub that permits rotation relative to the control and that is disposed on the proximal end of the tubular body. The Examiner identifies a "control or hub (66)" as equivalent structures. Office Action p. 2. Nash describes "a conventional Y connector 66 ... [that] has one input leg including a Touhy-Borst adjustable hemostasis valve 66A through which the atherectomy catheter 22 passes. The other input leg, i.e., the angled leg 68, is connected to the aspiration portion of the debris removal sub-system 30." Nash col. 8, ll. 12-18. Nash does not disclose, teach or suggest that the Y connector 66 is rotatable with respect to itself, and the Examiner's Office Action fails to identify any structure in Nash whatsoever corresponding to the recited claim limitations.

Therefore, it is respectfully submitted that Nash does not teach or suggest all the limitations of Claim 65, and withdrawal of the rejection under 35 U.S.C. § 102(e) is respectfully requested.

6. Independent Claim 68 is not anticipated nor rendered obvious by Nash

The Office Action rejects independent Claim 68 as being anticipated under 35 U.S.C. § 102(e) by Nash. Applicant respectfully submits that the Office Action fails to identify any

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teaching or suggestion from Nash upon which this rejection is based. Claim 68 recites, among other things, a “cutter capable of axial displacement relative to the control during operation.” Nash does not disclose, teach, or suggest a cutter that is capable of axial displacement with respect to a control during operation. In contrast, Nash states, “[t]he working head is located within a cylindrical shroud 56 (FIGS. 3 and 4) fixedly mounted on the front of the bushing 38.” Nash col. 7, ll. 14-16. The Nash cutter has a specific position within the shroud 56 to create a differential flow of infusate liquid to establish an unbalanced flow adjacent the working head to enable the catheter to be steered hydrodynamically and to aspirate debris from the working field of the instrument. Nash Abstract. Specifically, Nash states, “[t]he rotation of the working head about its longitudinal axis produces a powerful toroidal shaped vortex flow Q3 in the fluid contiguous with the working head. This flow Q3 circulates by entering into the shroud through the central or front opening 62 and exits out through the side window 64 as shown in FIG. 3.” Nash col. 7, ll. 35-40. If the Nash cutter is axially advanced or withdrawn, the device may not perform the intended function. Thus, Applicant respectfully submits that Nash fails to disclose, teach, or suggest a device in which the cutter is capable of axial displacement relative to a control and that the reference does not anticipate Claim 68 under 35 U.S.C. § 102(e).

Therefore, it is respectfully submitted that Nash does not teach or suggest all the limitations of Claim 68, and withdrawal of the rejection under 35 U.S.C. § 102(e) is respectfully requested.

7. Dependent Claims 2–10, 30–33, 61-64, 66–67, 69–71 and 74 are not anticipated nor rendered obvious by Nash

Claims 2–10, 30–33, 61-64, 66–67, 69–71, and 74 which depend from Claims 1, 21, 29, 60, 65 and 68, are believed to be patentable for the same reasons articulated above with respect to Claims 1, 21, 29, 60, 65 and 68, and because of the additional unique features recited therein. Accordingly, it is respectfully submitted that Nash does not teach or suggest all the limitations of these claims or the independent claims from which these claims depend, and withdrawal of the rejection under 35 U.S.C. § 102(e) is respectfully requested.

C. Conclusion

Applicant respectfully submits that the claims are in condition for allowance. Furthermore, any remarks in support of patentability of one claim should not be imputed to any

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other claim, even if similar terminology is used. Any remarks referring to only a portion of a claim should not be understood to base patentability on that portion; rather, patentability must rest on each claim taken as a whole. Applicant respectfully traverses each of the Examiner's rejections and each of the Examiner's assertions regarding what the prior art shows or teaches, even if not expressly discussed herein. Although changes to the claims have been made, no acquiescence or estoppel is or should be implied thereby; such amendments are made only to expedite prosecution of the present application and are without prejudice to the presentation or assertion, in the future, of claims relating to the same or similar subject matter.

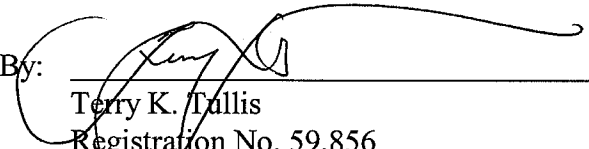
Applicant has made a good faith effort to respond to the outstanding Office Action and respectfully requests that a Notice of Allowance be issued at the earliest opportunity. Nevertheless, if any undeveloped issues remain or if any issues require clarification, the Examiner is cordially invited to contact Applicant's attorney, at the telephone number below, to resolve any such issue promptly so that extended prosecution of this application may be avoided.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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